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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/288,415 08/10/94 BRUGGER

EXAMINER

BAWA, R

ART UNIT	PAPER NUMBER
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4

1502
DATE MAILED:

10/13/95

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PATENT DEPARTMENT
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1501/1013

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-8 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-8 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1502

Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) The phrases "predetermined amount"; "full of a predetermined amount" and "especially approximately" are vague and indefinite because they are relative.

(2) The terms/phrases "preferably"; "especially" and "where appropriate" render the claims vague and indefinite.

(3) The term "substance mixture" is vague and indefinite because it is not art-recognized. It is unclear what the "mixture" is.

(4) The use of a trademark or tradenames in the claim to identify or describe a material or product not only renders a claim indefinite but also constitutes an improper use of the trademark or tradename. The definiteness problem associated with use of a trademark does not indicate whether the same material made using a differently trademarked product, infringes the claims.

Moreover, the value of a trademark is lost to the extent that it becomes descriptive of a product rather than an identification or a source or an origin of a product. Accordingly, the use of the trademark or tradenames FORMOTEROL in claim 7 is in improper use of the mark and/or name.

Art Unit: 1502

Definiteness of the above claim language has been analyzed, not in a vacuum, but in light of (1) the content of the application disclosure, (2) the teachings of the prior art and (3) the claim interpretation that would be given by one possessing an ordinary level of skill in this art at the time the invention was made. Since the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, this rejection is appropriate. *In re Wiggins*, 488 F2d 538, 179 USPQ 241 (CCPA 1973).

This application is informal in the arrangement of the specification.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of Specification

The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

- (a) Title of the Invention.
- (b) Cross-References to Related Applications (if any).
- (c) Statement as to rights to inventions made under Federally-sponsored research and development (if any).
- (d) Background of the Invention.
 - 1. Field of the Invention
 - 2. Description of the Prior Art.
- (e) Summary of the Invention.
- (f) Brief Description of the Drawing.
- (g) Description of the Preferred Embodiment(s).
- (h) Claim(s).
- (i) Abstract of the Disclosure.

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Art Unit: 1502

Claims 1-8 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to (i) delivery of corticosteroids (p. 2); (ii) the plastics coating being either polytetrafluoroethylene or perfluoroethylenepropylene (p. 2); (iii) the thickness of the plastics coating ranging from 1mm to 1mm (p. 2); (iv) the thickness of the container wall being 0.1mm to 2mm (p. 2); (v) 1ml-100ml being the volume of the interior of the container (p. 3); and (vi) the volume of the metering chambers is 5-400ul (p. 3). See M.P.E.P. §§ 706.03(n) and 706.03(z).

In the absence of the above limitations, undue experimentation would be required by the ordinary worker to practice the claimed invention. Claims are read in light of the specification, and the claims in this case are not commensurate in scope with the specification in the absence of these limitations.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raj Bawa, PhD, whose telephone number is (703) 308-2423. The examiner can normally be reached on Tuesday-Friday from 7:30a.m. to 6:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-5408.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.



**RAJ BAWA, PhD
PATENT EXAMINER
GROUP ART UNIT 1502**

Bawa:css
September 26, 1995